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*TD*

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|-----------------|-------------|----------------------|---------------------|
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09/427,873 10/27/99 BOYD

M 175912

HM12/0901

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SUITE 400  
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EXAMINER

LEE, L

ART UNIT

PAPER NUMBER

1645

DATE MAILED:

09/01/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.

09/427,873

Applicant(s)

Boyd

Examiner

Li Le

Group Art Unit

1645



☒ Responsive to communication(s) filed on Jan 18, 1998

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1035 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claim

☒ Claim(s) 20-27 is/are pending in the application

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 20-27 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 2

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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## DETAILED ACTION

### *Drawings*

1. This application has been filed with formal drawings. The drawings are objected to by the draftsman under 37 C.R.F. 1.84 or 1.152. See PTO-948 for details. Correction of the noted defects can be deferred until the application is allowed by the examiner.

### *Information Disclosure Statement*

2. Items listed on form PTO-1449 filed on 10/27/99 have been considered by the examiner.

### *Claim Rejections - 35 USC § 112*

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 20-27 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 20-27 are directed to a method of inhibiting a viral infection of a host by using the polypeptide of SEQ ID NO:2 which is isolated from *Nostoc ellipsosporum*. However, the

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specification does not sufficiently establish that the method can be used as claimed. Applicant's only evidence for inhibiting a viral infection is the in vitro test and there is insufficient evidence that such studies correlate with in vivo efficacy in anti-viral infection in a host. The in vitro assay is not an art-accepted model for a anti-viral infection or anti-HIV infection in a host. Nor has Applicant set forth any other evidence to establish that protein of SEQ ID NO:2 or it's conjugate with a viral envelope glycoprotein can be used to inhibit HIV or any viral infection in a host. It is well known in the art that viral infections in general, and HIV infections in particular, are refractory to anti-viral therapies, as taught by Fahey et al. These obstacles include: 1) the extensive genomic diversity and mutation rate associated with viruses, particularly with respect to the gene encoding the HIV envelope protein; 2) the fact that the modes of viral transmission include both virus-infected cells, which pass the infecting virus to other cells in a covert manner, as well as via free virus transmission; 3) the existence of a latent form of some viruses; 4) the complexity and variation of the pathology of viral infection in different individuals. The existence of these obstacles establish that the contemporary knowledge in the art would not allow one skilled in the art to use the claimed pharmaceutical compositions to inhibit a viral infection in a host without undue experimentation. It is clear from the evidence of Fahey et al that the ability to treat or inhibiting viral infection in a host is highly unpredictable and has met with very little success. Applicants have not provided any convincing evidence that their claimed invention is indeed useful as a method for inhibiting a viral infection in a host and have not provided sufficient guidance to allow one skilled in the art to practice the claimed invention

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without undue experimentation. In the absence of such guidance and evidence, the specification fails to provide an enabling disclosure.

*Status of Claims*

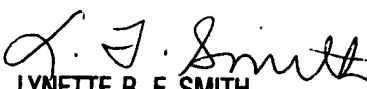
5. No claims are allowed. All claims stand rejected.

Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1645 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Li Lee whose telephone number is (703) 308-8891. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (703) 308-3909.

Li Lee  
August 30, 2000

  
LYNETTE R. F. SMITH  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600